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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,159	04/19/2007	Stig Bengmark	05822.0338USWO	8309
23552 7590 03/24/2010 MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			EXAMINER LUKTON, DAVID	
			ART UNIT 1654	PAPER NUMBER
			MAIL DATE 03/24/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/585,159	Applicant(s) BENCHMARK ET AL.	
	Examiner DAVID LUKTON	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15, 17-20, 22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) 6, 9-13, 15, 17-20 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 8 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicants' response filed 12/22/09 is acknowledged.

Claims 1-13, 15, 17-20, 22, 23 are now pending, claims 6, 9-13, 15, 17-20, 22 are withdrawn.

Claims 1-5, 7, 8, 23 are examined in this Office action.

. . . .

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. (see page 8, line 11, specification). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

▲

The following is a quotation of 35 USC, §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each

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claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1-5, 7, 8, 23 are rejected under 35 U.S.C. §103 as being unpatentable over Haynes (USP 5,246,707).

As indicated previously, Haynes discloses (col 4, line 60+) an equal weight mixture of polyarginine and polyglutamic acid.

In response, applicants have argued that Haynes does not disclose a pharmaceutically acceptable carrier. However, water qualifies as such. Moreover, if the water also contains ingredients which would be non-toxic if administered to a rat, such a mixture would generally fall within the scope of a “pharmaceutically acceptable carrier”.

Applicants have also argued that the phrase “barrier network” cannot be found anywhere in the reference. However, as applicants will no doubt agree, the mere act of combining a cationic peptide with an anionic peptide with a liquid carrier will produce a “barrier network”. The fact that a practitioner of the Haynes invention might not choose to invoke the phrase at issue does not detract from its physical properties.

▲

Claims 1-5, 7, 8, 23 are rejected under 35 U.S.C. §103 as being unpatentable over Nimni (USP 4,378,224).

As indicated previously, Nimni discloses (e.g., col 4, line 11+; col 8, line 10+; col 9, line 3+) a mixture that comprises a block copolymer of poly-Lys and poly-Glu, or a mixture of poly-Lys and poly-Glu.

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In response, applicants have argued that Ninmi mandates that the poly-Lys and poly-Glu be covalently bonded to implant tissue. Applicants, however, have declined to identify the passage where this might be stated.

Applicants have also argued that the phrase “barrier network” cannot be found anywhere in the reference. However, as applicants will no doubt agree, the mere act of combining a cationic peptide with an anionic peptide with a liquid carrier will produce a “barrier network”. Furthermore, to the extent that a mixture of poly-Lys and poly-Glu can act as a barrier network at all, it will be more effective in the case of the Ninmi application than it will when a mixture of the two peptides is sitting in a flask with some water. No doubt applicants are of the view that if one tosses a few grams of poly-Lys into a beaker containing water, and then adds some poly-glu, the resulting mixture will somehow act as a barrier to something. In view of this rather unconventional notion, it’s difficult to make the case that the poly-Lys and poly-Glu mixture (of the reference) will fail to act as a barrier, particularly when it is indeed effective to fill interstitial gaps of a matrix.

The rejection is maintained.

▲

Claims 1-3, 5, 7, 8, 23 are rejected under 35 U.S.C. §103 as being unpatentable over “Isoelectric Focusing, Principles and Methods”, pages 128-129 (Pharmacia Fine Chemicals, Uppsala Sweden, 1982).

As indicated previously, the Pharmacia information brochure on isoelectric focusing discloses what is well known to analytical biochemists, i.e., that marker proteins can be

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used to assist in the determination of isoelectric point of a given protein. As disclosed, the marker proteins can span a range of isoelectric points, e.g., from pI 4.5 to pI 8.5.

In response, applicants have argued that the reference does not disclose a pharmaceutically acceptable carrier. However, the analytical biochemist of ordinary skill would recognize that the peptides would have to be dissolved in an aqueous medium before applying to the gel.

Applicants have also argued that the phrase “barrier network” cannot be found anywhere in the reference. However, as applicants will no doubt agree, the mere act of combining a cationic peptide with an anionic peptide with a liquid carrier will produce a “barrier network”. The fact that a biochemist preparing a mixture of a cationic peptide and an anionic peptide in water might not choose to invoke the phrase at issue does not detract from its physical properties.

▲

Claims 1-3, 5, 7, 8, 23 are rejected under 35 U.S.C. §103 as being unpatentable over “Isoelectric Focusing, Principles and Methods”, pages 128-129 (Pharmacia Fine Chemicals, Uppsala Sweden, 1982) in view of any of the following: USP 3901780, USP 3664939, USP 3915839, or USP 4204929.

The teachings of the primary reference were indicated previously. The passage provided by the examiner, however, does not discuss basic principles of isoelectric focusing. The secondary references are provided for the benefit of those who may be unfamiliar with the technique.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

/David Lukton/

Primary Examiner, Art Unit 1654